REMARKS

Claims 1-6 and 9-12 are currently pending in the application. Claims 1, 9, 10, and 12 are in independent form.

Claims 1-6 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of preventing RSV infection, does not reasonably provide enablement for a method whereby any respiratory infection is prevented. More specifically, the Office Action states that if the respiratory infection agent was other than a respiratory virus, the claims would be improperly set forth since the infection *per se* would not be prevented by the instant method. In order to further prosecution, the claims have been amended to recite that the method prevents a viral respiratory infection. Further, the Office Action states that the specification fails to enable the administration of an agent orally or by inhalation, since the mode of administration is agent-dependent. In order to further prosecution, the claims have been amended to recite that the agent may be administered orally or via inhalation if that agent is able to be orally administered or inhaled. Reconsideration of the rejection is respectfully requested.

Claims 1, 2, 3, and 10-12 stand rejection under 35 U.S.C. § 102(b) as being anticipated by the Patel et al. reference. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by the Patel et al. reference, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

The Office Action states that the Patel et al. reference teaches that respiratory epethelial cells are the primary target cells for RSV infection and produce proinflammatory and immunoregulatory cytokines and express adhesion molecules, suggesting that the respiratory epithelial cell may be the most important cell to regulate the initial stages of inflammation and host immune responses in the microenvironment of the respiratory mucosa. Further, the Patel et al. reference teaches that simultaneous incubation of infectious purified RSV with sIL-1r resulted in a significant reduction in enhancement of ICAM-1 expression. This therefore suggests that sIL-1r blocks ICAM expression. The experiments alone do not suggest that sIL-1r, or blocking of ICAM expression, can reduce the severity of RSV disease. It can be interpreted from these studies that since ICAM-1 is a proinflammatory molecule, by blocking ICAM-1, the RSV induced inflammation is decreased. The present invention instead establishes that by blocking ICAM-1, the viral replication and spread in the epithelial cells of the lungs is limited. The antiviral mechanism of the ICAM-1 antibody or soluble ICAM-1 has not been previously demonstrated. The significant reduction in the number of infected cells or in viral titers of infected cultures leads to the reduction of ICAM-1 and other proinflammatory cytokines such as IL-1β. This finding enables the use of blockers of ICAM-1 for the purpose of limiting viral titers, similar to that of a vaccine. That the blockers would work similar to that of a vaccine was neither shown nor suggested by the Patel et al. reference. Therefore, the Patel et al. reference does not establish a method for preventing RSV infection, and the claims of the presently pending application are patentable over the Patel et al. reference. Reconsideration of the rejection is respectfully requested.

Claims 1 and 2 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Kumasaka et al. reference. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by the Kumasaka et al. reference, as applied to the claims, is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

The Office Action states that the Kumasaka et al. reference teaches that antisense oligonucleotides inhibited upregulation of ICAM-1 expression induced by intratracheal instillation of endotoxin into the distal airway, subsequently preventing the acute inflammatory response. It is undisputed that the Kumasaka et al. reference teaches that antisense oligonucleotides inhibited upregulation of ICAM-1 expression by instillation of endotoxin. The effect of endotoxin is not equivalent to the effect of RSV. Endotoxins are typically produced by gramnegative bacteria and RSV does not produce endotoxins. The Kumasaka et al. reference does not pertain to RSV infection, nor does it pertain to a viral respiratory infection and methods of preventing and treating such an infection. Therefore, the presently pending claims are patentable over the Kumasaka et al. reference and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above. The prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on August 16, 2002.

Connie Herty

VERSION WITH MARKINGS TO SHOW CHANGES MADE

CLAIMS:

1. A method of preventing a viral respiratory infection by administering an effective amount of an agent for down-regulating ICAM-1 expression in a pharmaceutically acceptable carrier.

4. The method according to claim 1, wherein said administration further includes administering the agent by inhalation when the agent is capable of inhalation administration.

5. The method according to claim 2, wherein said administration step further includes administering the agent orally when the agent is capable of oral administration.